REMARKS/ARGUMENTS

The Patent Office examines and rejects claims 1-16, 49-58, 62-79 and 81-87. Applicants amend independent claims 1, 49 and 54 to incorporate limitations of claims 2 and 4. Applicants cancel claims 2, 4, and 50. Applicants amend claims 3 and 51 to have proper dependencies. Applicants amend claims 63 and 77, as supported at least by claim 58 and paragraphs 35 and 57 of the application. Applicants amend claim 82 and submit additional claims 88-89 as supported at least at paragraphs 35, 48, 64-65 and 74-83 (see particularly paragraphs 79-82 for additional claim 89) and Fig. 6 of the application. Applicants amend paragraph 6 of the application to indicate that "On-Board Imager" is a registered trademark of Varian Medical Systems, Inc. Thus, Applicants submit that no new matter is added herein.

Hence, Applicants respectfully request reconsideration of the pending claims in view of the remarks herein.

Claims Rejected Under 35 U.S.C. §103

The Patent Office rejects claims 1-3, 5-7, 13-14, 16, 49-58, 62, 76-77, 82, 84 and 87 under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2002/0193685 to Mate et al. (Mate) in view of U.S. Publication No. 2002/0065461 to Cosman (Cosman). Claims 4 and 83 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman as applied to claim 1 above, and further in view of U.S. Patent Pub. No. 2003/0007601 to Jaffray et al. (Jaffray). Claims 8-9, 12, 78-79 and 81 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman as applied to claims 6-7 above, and further in view of U.S. Patent No. 5,757,953 to Jang (Jang). Claims 10-11 are rejected under 35 U.S.C. §103(a) as unpatentable over Mate in view of Cosman and Jang as applied to claim 8 above and further in view of U.S. Patent No. 5,446,548 to Gerig et al. (Gerig). Claims 15, 63-72 and 74 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman as applied to claims 1 and 14 above, and further in view of U.S. Patent No. 6,073,044 to Fitzpatrick et al. (Fitzpatrick). Claims 73 and 75 are rejected under 35 U.S.C. §103(a) as being unpatentable over Mate in view of Cosman and Fitzpatrick as applied to claim 64 above, and further in view of US Patent No. 5,622,187 to Carol ("Carol"). Claims 85-86 are rejected under 35 U.S.C. §103(a) as

being unpatentable over Mate in view of Cosman as applied to claims 1 and 58 above, and further in view of U.S. Patent No. 6,398,710 to Ishikawa et al. ("Ishikawa"). For a claim to be obvious every limitation of that claim must be taught by at least one property combined reference.

Applicants respectfully disagree with the rejection above and submit that independent claim 1 is patentable over the cited references for at least the reason that none of the references teach imaging a plurality of markers in a first and in a different second imaging modality, wherein at least a plurality of the markers are implanted completely internally in a body; and determining first coordinates and second coordinates and internal to the body, wherein at least a plurality of said markers are implanted in soft tissue of the body, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging, as required by claim 1.

Applicants would like to thank the Patent Office for the explanation in the last paragraph of page 9 through first paragraph of page 10 of the current Office Action. Applicants have updated the claims (e.g., claim 82) and response to remove the confusion. However, Applicants respectfully disagree that, other than based entirely on Applicants claims, any practitioner would find motivation for, or enabled embodiments of, a combination of the implanted excitable markers located with RF sensors of Mate (see Figs. 1-7) with the external, camera imaged markers of Cosman (see Figs. 1-3). Clearly, it is not possible for these two types of markers to be combined into a single marker embodiment, as the implanted excitable marker of Mate is unable to satisfy the external camera visible marker of Cosman; and the external camera visible marker of Cosman is unable to be the implanted excitable marker located with an RF sensor of Mate. In fact, Mate teaches against using external markers (see Mate paragraphs 7-8) by discouraging or otherwise criticizing the use of external markers (see the end of paragraph 8) (Depuy Spine, Inc. v Medtronic Sofoamor Danek, Inc. (CFAC Docket 2008-1240, -1253, -1401, decided June 1, 2009, page 14-15 (also see MPEP 2141.02 and 2143.01)).

Next, Applicants would like to thank the Patent Office for the explanation in the second paragraph of page 9 noting that the question isn't whether a reference "requires" a certain feature, but whether the feature would be obvious. Applicants agree and understand this. What Applicants are trying to say (as described further herein) is that there is no benefit, use, or reason for the art to be taken in combination. Mate uses implanted excitable markers that are located with RF sensors, which can not sense non-excitable markers, such as the markers of Cosman. Conversely, Cosman teaches markers visible to a camera which can not sense optically invisible markers, such as the markers of Mate (Mate teaches against using external markers at paragraphs 7-8). The primary purpose of Mate is to image a target and markers 30 around the target so that during treatment, the markers can be excited with excitation source 32 to resonate at a low energy radial-frequency magnetic signal measurable from outside the body, in order to ensure proper positioning of the target (see Mate paragraphs 35-39 and 60-62). Thus, there is no use, benefit or motivation for a practitioner to add a second imaging modality to Mate. Moreover, a practitioner would not attempt to combine the external fiducial markers (e.g., markers 20, 21, 23 and 24) or implanted markers mentioned in Cosman (see Cosman paragraphs 31 and 67) with Mate because (1) Mate is not helped by surface mounted markers (see paragraphs 65-68) and (2) Mate is not helped by additional internal markers in addition to markers 30 (see Mate paragraphs 60-62). Thus, Applicants assert that the combination of Mate with Cosman is impermissible hindsight and is not enabled.

Next, even if it were possible to combine Mate with Cosman, which Applicants clearly do not believe is possible, the combined marker (e.g. implanted excitable and visible to a camera) and imaging systems (e.g. RF sensors and visible imaged camera) would still not teach the claim 1 limits, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging. Specifically, at paragraph 67, Cosman only teaches that diagnostic X-rays from machines, or high energy X-rays for portal imaging can be used to visualize markers prior to treatment. However, this does not conceive of imaging using a second imaging modality that is one of kV and MV imaging, in addition to imaging using CT, as required by claim 1.

Moreover, the combination of Mate with Cosman would result in the anchored externally visible markers of Cosman combined with the RF sensors of Mate, which still doesn't disclose or suggest the claimed markers that are implanted completely internally to a body, and imaged using CT, and imaged using kV or MV imaging, as required by claim 1. That is, neither the implanted excitable markers of Mate, the camera visible markers of Cosman, nor the combination teach the above noted markers of claim 1. Notably, neither reference coordinates images from two different imaging modes. In addition, Mate teaches against using external markers (see Mate paragraphs 7-8) by discouraging or otherwise criticizing the use of external markers (see the end of paragraph 8) (Depuy Spine, Inc. v Medtronic Sofoamor Danek, Inc. (CFAC Docket 2008-1240, -1253, -1401, decided June 1, 2009, page 14-15 (also see MPEP 2141.02 and 2143.01)).

Next, Applicants respectfully note that the Patent Office appears to cite Official Notice in the second paragraph of page 9 of the current Office Action. For example, paragraph 74 of Mate does not mention any specific monitoring system, apparatus, or method; or any limit of the claims. Consequently, Applicants respectfully request the Patent Office provide a reference in support of this Official Notice teaching the limits of the claims, in accordance with MPEP 2144.03.

Moreover, it is noted that in this argument the Patent Office appears to cite Official Notice that does not predate the filing of the current application (e.g. "There are a wide variety of different techniques..."). Thus, this Official Notice is improper.

Moreover, Mate fails to teach determining first and second coordinates relative to beam isocenters; correlating the second coordinates with the first coordinates; and calculating an offset between the first coordinates and the second coordinates for at least one of the plurality of markers as required by claim 3. As noted on page 4 of the current Office Action, Mate fails to show using more than one imaging modality to determine coordinates of markers beam isocenters. Next, Mate fails to teach the false markers of claim 12; the gantries of claim 60; or the limitations of claims 85-86.

Moreover, Cosman does not teach determining coordinates of the same set of completely internal markers relative to a first and second beam isocenter; correlating the second coordinates

with the first coordinates; and calculating an offset between the first coordinates and the second coordinates for at least one of the plurality of markers as required by claim 3. Next, Cosman fails to teach the non-marker objects of claim 12; the gantries of claim 60; or measuring radiation received by the markers of additional claims 85-86. For example, Cosman does not provide enough detail in paragraph 67 to enable any of the above noted claims.

Applicants also disagree with the rejection above of independent claims 49 and 54 for at least the reason that the cited references do not teach imaging markers in a first and second imaging modality, wherein at least a plurality of the markers are implanted completely internally in a body; and determining first coordinates and second coordinates and internal to the body, wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the different second beam isocenter is a high energy beam of radiation of a treatment machine, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging, as required by amended claims 49 and 54.

Mate teaches a primary purpose of allowing target 12 to be accurately positioned at a treatment machine isocenter by acceptably aligning target and machine isocenters 40 and 22 for radiation delivery from source 18 to irradiate a target (see paragraphs 35 and 39). Mate teaches that imaging data from a CT, MRI, or ultra-sound imaging system may be used to provide a simulated model of the target, the markers, and the target isocenter during simulation (see paragraph 60) and that images of tumor 90 and markers 30 can be obtained by CT, MRI, ultra-sound or other imaging techniques to monitor the status of the target, such as a tumor and the like, in a patients body 14 over time (see paragraph 62). However, as noted on page 4 of the current Office Action, Mate fails to show using more than one imaging modality to determine coordinates of markers relative to beam isocenters, as required by claims 49 and 54. Instead, Mate teaches that markers can be located by exciting markers 30 with excitation source 32 so that markers 30 resonate at a selected unique frequency and generate an underlying low energy radial-frequency magnetic signal measurable from outside body 14 by array 34 of sensors 36 (see paragraph [0036]). Thus, Mate does not teach imaging a plurality of markers in a first and in a

different second imaging modality and internal to a body, wherein at least a plurality of the markers are implanted in a body; and determining first coordinates and second coordinates, wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging as required by claims 49 and 54.

The primary purpose and principle of operation of Cosman is to coordinate external markers for external treatment apparatus to specific targets within the body (see paragraphs 8 and 9). The camera of Cosman images the external markers relative to photons reflected from the external markers (see paragraphs 31 and 102). For example, Cosman teaches percutaneously fixing a stud section to the iliac crest bone of the pelvis during treatment, so that an array of external marker spheres can be attached to the stud above the surface of the skin at the time of treatment (see paragraph [0061] and Figure 3C). The markers are geometric objects to indicate positions of locations that are visible to a camera (see paragraph [0063]). Cosman also mentions that refinement of internal target positioning can be achieved by x-ray imaging components 80 and 81 aligned on axes 14 and 12 to determine a digital image of x-ray through a patients body (see paragraph 67) and that a portal imager 85 can provide a digital image from high energy x-rays emitted from collimator 5 (see paragraph 67). Thus, diagnostic x-rays from machines 80 and 81 or high energy x-rays for portal imaging can be used to visualize markers implanted in bones or tissue within the patient prior to treating (see paragraph 67). However, Cosman does not teach or enable determining coordinates of the same set of completely internal markers relative to a first and second beam isocenter as required by claims 49 and 54. Instead, Cosman only provides coordinating the location of externally visible fiducial markers that can be scanned by a camera (see paragraphs 24, 29-34, 39-41, 52, 61 and 68). For example, the primary purpose of Cosman is to have the markers external to the skin so that they can be imaged with a camera in order to provide an optical tracking system to compare the location of the markers in images picked up a camera system to align the target with the isocenter of a beam (see paragraphs [0064]-[0066] and Figure 3C). However, Cosman does not teach determining first coordinates

and second coordinates, wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the different second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging as required by claims 49 and 54 because Cosman does not coordinate images from the same set of completely internal markers from two different imaging modes.

In addition, by imaging markers wherein at least a plurality of the markers are residing completely internally in a body in two modalities, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging as required by the independent claims, some embodiments described in the specification, for example, without limitation thereto, may provide one or more of: (1) the benefit of imaging in an x-ray imaging modality is an isocenter of an x-ray image system, and imaging in a second x-ray imaging modality using a high energy beam of radiation of a treatment machine (see paragraphs [0043], [0048] and [0055]-[0057] and [0074] of the Application; and claims 49 and 54); and (2) setting up a treatment plan using CT images of anatomy, tumor, and the markers; and then using kV and/or MV imaging to quickly, properly position a patient during treatment to ensure accurate placement of the tumor based on the imaged markers, for irradiating the tumor with the treatment beam (see at least paragraphs 53-54 of the Application; and claims 62-75 and 82-84; and new claims 88-89). However, the references do not contemplate or enable such benefits.

The dependent claims must be considered in their entirety. For instance, in addition to being dependent upon allowable base claims, Applicants disagree with the rejection above of claim 62 for at least the reason that the references do not teach the above noted limitations of imaging in a first and second modality claim 1, as well as adjusting the position of a target volume relative to a treatment beam using the plurality of internal markers imaged using the first and second imaging modalities, as required by claim 62. Mate only teaches positioning a target

for treatment radiation delivery (see paragraph 35 and 39) using implanted excitable markers located with RF sensors (see Figs. 1-7). Cosman only teaches that diagnostic X-rays or high energy X-rays can be used to visualize markers prior to treatment (see paragraph 67). Thus, references do not contemplate adjusting a position of a target volume relative to a treatment beam using markers imaged using a first and second modality, as required by claim 62.

In addition to being dependent upon allowable base claims, Applicants disagree with the rejection above of claim 63 for at least the reason that the references do not teach the above noted limitations of imaging in a first and second modality claim 1, as well as estimating an adjustment to at least one of the body and a treatment beam in a treatment session, based on a determination of any change of spacing between imaged markers implanted in a target, over a course of multiple treatment sessions, as required by claim 63. Mate only teaches positioning a target for treatment radiation delivery (see paragraph 35 and 39) using implanted excitable markers located with RF sensors (see Figs. 1-7). Cosman only teaches that diagnostic X-rays or high energy X-rays can be used to visualize markers prior to treatment (see paragraph 67). Thus, the references do not contemplate estimating an adjustment to at least one of the body and a treatment beam in a treatment session, based on a determination of any change of spacing between imaged markers implanted in a target, over a course of multiple treatment sessions, as required by claim 63.

In addition to being dependent upon allowable base claims, Applicants disagree with the rejection of claim 66 for at least the reason that the references do not teach the above noted limitations of imaging in a first and second modality claims 1 and 63, as well as estimating a patient position adjustment in a treatment session, based on a determination of any change of spacing between imaged markers, over a course of treatment, as required by claim 66. Mate only teaches positioning a target for treatment radiation delivery (see paragraph 35 and 39) using implanted excitable markers located with RF sensors (see Figs. 1-7). Cosman only teaches that diagnostic X-rays or high energy X-rays can be used to visualize markers prior to treatment (see paragraph 67). Thus, the references do not contemplate the above noted limits of claim 66 considered in its entirety.

In addition to being dependent upon allowable base claims, Applicants disagree with the rejection of claim 67 for at least the reason that the references do not teach the above noted limitations of imaging in a first and second modality claims 1 and 63, as well as estimating a Multi-Leaf Collimator (MLC) position adjustment in a treatment session, based on a determination of any change of spacing between imaged markers, over a course of treatment, as required by claim 66. Mate only teaches positioning a target for treatment radiation delivery (see paragraph 35 and 39) using implanted excitable markers located with RF sensors (see Figs. 1-7). Cosman only teaches that diagnostic X-rays or high energy X-rays can be used to visualize markers prior to treatment (see paragraph 67). Thus, the references do not contemplate the above noted limits of claim 67 considered in its entirety.

In addition to being dependent upon allowable base claims, Applicants disagree with the rejection of claim 77 for at least the reason that the references do not teach the above noted limitations of imaging in a first and second modality claim 1, as well as that the imaging sources of the first and second imaging modalities are located on two or more gantries, as required by amended claim 77. Mate only teaches positioning a target for treatment radiation delivery (see paragraph 35 and 39). Cosman only teaches using X-rays to visualize implanted markers prior to treatment (see paragraph 67). Consequently, the references do not contemplate imaging markers using sources from two or more gantries, as required by claim 77.

In addition to being dependent upon an allowable base claim, Applicants disagree with the rejection of claim 82 for at least the reason that the references do not teach that the first beam isocenter is determined at a treatment planning machine during a treatment planning stage, the second beam isocenter is a treatment machine beam isocenter during treatment, and the treatment planning machine and the treatment machine are different machines, as required by amended claim 82. Mate only teaches positioning a target for treatment radiation delivery (see paragraph 35 and 39). Cosman only teaches using X-rays to visualize implanted markers prior to treatment (see paragraph 67). Consequently, the references do not contemplate the above noted limits of claim 82 considered in its entirety.

In addition to being dependent upon an allowable base claim, Applicants disagree with the rejection of claim 84 for at least the reason that the references do not teach that one imaging

source of the first imaging modality is located on a gantry of a treatment planning machine, and an imaging source of the second imaging modality is located on a different treatment machine, as required by amended claim 82. Mate only teaches positioning a target for treatment radiation delivery (see paragraph 35 and 39). Cosman only teaches using X-rays to visualize implanted markers prior to treatment (see paragraph 67). Consequently, the references do not contemplate the above noted limits of claim 84 considered in its entirety.

In addition to being dependent upon an allowable base claim, at least the arguments above for claim 84 apply to show that additional claims 88-89 are not taught by the references.

In addition to being dependent upon allowable base claim 1, Applicants disagree with the rejection above of claims 85-86 for at least the reason that the combination of Ishikawa with Mate or Cosman is improper since the primary purpose of the markers in Mate is to be excitable by excitation source 32 so that they provide a low energy radial-frequency magnetic signal measurable from outside the body (see paragraph 36). Thus, a practitioner would not be motivated to, and would not be able without undue experimentation to combine the magnetic signal markers of Mate with the radio-frequency markers of Ishikawa because the magnetic and radio-frequency signal would interfere with each other based on electromagnetic wave principles of physics. Moreover, a practitioner would not be motivated to, and would not be able without undue experimentation to combine the external fiducial markers that may be LED emitters, reflectors of light, reflecting spheres...of Cosman (see paragraph 31) with the radio-frequency markers of Ishikawa. Finally, the motivation cited by the Patent Office for this combination of references appears to be gleaned only from Applicants claims.

Any dependent claims not mentioned above are patentable over the cited references for at least the reasons provided above of their base claims as well as for additional limitations of dependent claims.

Hence, Applicants respectfully request withdrawal of all the rejections above for all of the claims.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Jessica Huester 2010-06-07

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